

insignificant amounts ... of more than one-half the nutrients required \* \* \* to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.” Current regulations considered 13 required nutrients (calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron) and calculated “more than one-half” to mean that seven or more nutrients must be at insignificant levels for a product to use the simplified format (58 FR 2709 at 2140, comment 173). Accordingly, in conformance with the statutory requirements, the inclusion of *trans* fat as a mandatory nutrient results in a total of 14 required nutrients. This new total necessitates changing the number of nutrients that must be present in insignificant amounts in § 101.9(f) from seven to eight to qualify a food for the simplified format. Therefore, FDA is revising § 101.9(f) to state “The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of eight or more of the following: Calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron \* \* \*”

FDA is modifying sample labels throughout § 101.9 to be consistent with the revisions described previously. The citations for the sample labels that have been modified are as follows: § 101.9(d)(11)(iii) (the tabular display of the nutrition label), paragraph (d)(12) (the full nutrition label), paragraph (d)(13)(ii) (an example of an aggregate nutrition label), and paragraph (e)(5) (nutrition information presented for a food “as purchased” and “as prepared”). Likewise, the sample labels in § 101.9(j)(13)(ii)(A)(1) and (j)(13)(ii)(A)(2) (tabular display and linear displays, respectively, of nutrition labels for foods in packages with a total surface area available to bear labeling of 40 or less square inches) are also being revised to include *trans* fat.

Other conforming amendments to § 101.9 that are required as a result of this rulemaking include revisions to paragraphs (g)(5) and (g)(6) that inform the industry of how FDA will determine compliance with this section. Paragraph (g)(5) addresses those nutrients for which dietary guidance generally recommends limitations on intake. Accordingly, FDA will include *trans* fat as one of the nutrients that are deemed to be misbranded under section 403(a)

of the act if the nutrient content of the composite sample is greater than 20 percent in excess of the value for that nutrient declared on the label. Likewise, § 101.9(g)(6) is being revised to state that reasonable deficiencies in a food of calories and specified nutrients, including *trans* fat, under labeled amounts are acceptable within current good manufacturing practice.

Section 403(q)(5)(F) of the act specifies that dietary supplement products shall bear nutrition labeling “in a manner which is appropriate for the product and which is specified in regulations...” Accordingly, FDA issued regulations in § 101.36 that specify the nutrition information that must be on the label or labeling of dietary supplements (62 FR 49826, September 23, 1997). In the November 1999 proposal, FDA proposed to amend § 101.36 to maintain consistency in the nutrition labeling of conventional foods and of dietary supplements. Comments unanimously supported revising § 101.36 to be consistent with § 101.9 as it pertains to the provisions for *trans* fat. Accordingly, FDA is revising paragraph § 101.36(b)(2)(i) to provide for *trans* fats in the nutrition labeling of dietary supplements.

This final rule also impacts on the voluntary nutrition labeling program of raw fruits, vegetables, and fish in that § 101.45(a)(2) requires that nutrients be declared in accordance with § 101.9. However, because section 403(q)(4)(A) of the act requires the Secretary, and by delegation FDA, to furnish nutrition information for that program and the agency has proposed to update those values (67 FR 12918, March 20, 2002), the agency is deferring action on § 101.45 until a final rule is published on that rulemaking.

### C. Definition of Trans Fatty Acids

In the November 1999 proposal, FDA defined *trans* fatty acids as “unsaturated fatty acids that contain one or more isolated (i.e., nonconjugated) double bonds in a *trans* configuration (64 FR 62746 at 62757).

(Comment 19) Most of the comments on the definition of *trans* fat supported the proposed definition that excludes fatty acids with conjugated bonds, stating that *trans* fatty acids with conjugated bonds are metabolized differently than those with nonconjugated bonds and that this definition adequately identifies the fatty acids intended to be covered by the rule. A few comments recommended that *trans* fatty acid precursors of conjugated linoleic acid (CLA) should also be excluded from the definition. These comments noted that *trans*-vaccenic

acid (*trans*-11 18:1), which is the dominant *trans* fatty acid in products of ruminant origin (e.g., cows’ milk), can be desaturated in the body and converted to CLA. For this reason, the comments recommended that *trans* fatty acids of ruminant origin not be included in the definition of *trans* fatty acids.

Other comments stated that *trans* fatty acids with conjugated bonds should be included in the definition of “*trans* fatty acids.”

Another comment requested that FDA explicitly state that the rules on the labeling and claims for *trans* fatty acids apply equally to naturally occurring *trans* fats.

FDA notes that the comments requesting that *trans* vaccenic acid and other *trans* fatty acids of ruminant origin be excluded from the definition of *trans* fatty acids and that fatty acids with conjugated bonds be included focused on functional or metabolic aspects of these compounds (e.g., their metabolic transformations to other types of fatty acids) rather than on their actual chemical structures. Since most of the comments agreed with the proposed definition, which identifies *trans* fatty acids by their chemical structures, the agency is taking no action in response to suggestions to define *trans* fatty acids by their functional attributes. Thus for the purposes of this rule, the origin of the *trans* fatty acid does not matter.

*Trans* vaccenic acid, a *trans* fatty acid with a single double bond, and other *trans* fatty acids of ruminant origin with either a single double bond or nonconjugated double bonds are included in this chemical definition of *trans* fatty acids. *Trans* fatty acids with conjugated bonds will not be included because they do not meet the Agency’s regulatory chemical definition of *trans* fatty acids which is “all unsaturated fatty acids that contain one or more isolated double bonds in a *trans* configuration.” FDA notes also that while the proposal combined saturated fat and *trans* fatty acids on a single line, this final rule provides for a separate line for *trans* fat. The declarations of saturated fat and *trans* fat will now be separate and both declarations will be based on chemical definitions of these components. Again, *trans* fatty acids, regardless of origin, that meet the above definition are to be included in the label declaration of *trans* fat.

FDA notes that, in classifying fatty acids, the IOM report on macronutrients uses a chemical definition of *trans* fatty acids that differs from FDA’s regulatory chemical definition. The IOM report includes all fatty acids with a double bond in the *trans* configuration in the broad category of *trans* fatty acids (Ref.